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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,565

04/17/2007

Roberto Oliva

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EXAMINER

YOUNG, RACHEL T

ART UNIT

PAPER NUMBER

3771

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,565	Applicant(s) OLIVA, ROBERTO	
	Examiner RACHEL T. YOUNG	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment

1. This office action is responsive to the amendment filed on 12/16/09. As directed by the amendment: claims 1 and 3-9 have been amended, claim 2 has been canceled, and no new claims have been added. Thus, claims 1 and 3-9 are presently pending in the application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 and 3-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1, line 18 recites “longitudinal axis **substantially** perpendicular”, however this further limitation of substantially perpendicular is not in the original disclosure and is considered new matter.

Claim Rejections - 35 USC § 103

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4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knupp et al. (5,396,883) in view of Anderson et al. (6,065,472).

Regarding claim 1, in fig. 1 and 3 Knupp discloses a first body 12, including an inhaling channel (through 12 passageway, into the page in fig. 3) extending through and along a longitudinal axis of the first body; and a second body (20 and C) including a receptacle (within 12 and 20), the first body is inserted into the receptacle, the inhaling channel has a lateral outlet 24 inside the receptacle facing perpendicular to the longitudinal axis of the first body, the second body includes at least one reservoir (Fig. 1, C), which is having an opening (passage of 22) to the receptacle and containing at least one dose of preparation (nebulizer cup C must contain a therapeutic substance of

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some kind to be nebulized, Col. 1, ll. 10), said reservoir extends along a longitudinal axis substantially perpendicular (from top to bottom of 12) to the longitudinal axis of the first body, and the first body rotates about its own longitudinal axis with respect to the second body (Fig. 3-Fig. 3) between a first position (Fig. 4), at which the lateral outlet of the inhaling channel does not connect with the opening of the reservoir and the reservoir is not connected to the inhaling channel, and a second position (Fig. 3), in which the lateral outlet of the inhaling channel connects the opening of the reservoir and the reservoir is connected to the inhaling channel. Knupp is silent regarding that the medicament is a powder. Anderson teaches a powder medicament (Col. 5, ll. 23). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Knupp's medicament with a powder medicament, as taught by Anderson, for the purpose of providing a better delivery to the lungs. It appears that Knupp would perform equally as well with a powder medicament as with another medication, since the medication is being nebulized.

Regarding claim 5, Knupp discloses the claimed invention, but is silent regarding that the inhaling channel has one first protrusion, which protrudes transversely to the longitudinal axis of the first body from the lateral surface of the inhaling channel toward the inside of said inhaling channel. However, in fig. 4 Anderson teaches that the inhaling channel has at least one first protrusion 26, which protrudes transversely to the longitudinal axis of the first body from the lateral surface of the inhaling channel toward the inside of said inhaling channel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Knupp's inhaling

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channel with a first protrusion, as taught by Anderson, for the purpose of delivering the powder directly to the user's respiratory tract and not into the cheek cavity of the user (Col. 5, ll. 22-24).

Regarding claim 6, Knupp discloses the claimed invention, but is silent regarding that the inhaling channel has a second protrusion, which protrudes transversely to the longitudinal axis of the first body from the lateral surface of the inhaling channel toward the inside of said inhaling channel, said second protrusion being spaced with respect to the first protrusion toward the longitudinal axis of the first body and being arranged opposite with respect to a central plane of the inhaling channel. Anderson teaches a second protrusion 25, which protrudes transversely to the longitudinal axis of the first body from the lateral surface of the inhaling channel toward the inside of the inhaling channel, the second protrusion being spaced with respect to the first protrusion toward the longitudinal axis of the first body and being arranged opposite with respect to a central plane of the inhaling channel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Knupp's inhaling channel with a second protrusion, as taught by Anderson, for the purpose of delivering the powder directly to the user's respiratory tract and not into the cheek cavity of the user (Col. 5, ll. 22-24).

Regarding claim 7, the modified Knupp discloses from the rejected claims 5 and 6 first and second protrusions having a surface that is inclined and blended with the lateral surface of the inhaling channel, the surfaces that are inclined and blended with

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the lateral surface of the inhaling channel being directed toward the second outlet of the inhaling channel.

Regarding claim 8, Knupp discloses that the second body is provided with a through hole 26, which faces the opening of the reservoir.

7. Claims 3-4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knupp/Anderson as applied to claim 1 above, and further in view of Thompson.

Regarding claim 3, the modified Knupp discloses an inhaling channel, a first outlet (H to the left of 14) and a second outlet (H to the right of 14) that are arranged approximately at right angles to the longitudinal axis of the first body, but is silent regarding that the end at which the second outlet is arranged being in contact with an end wall of the receptacle that is perpendicular to the longitudinal axis. However, Thompson teaches a first and second out arranged approximately at right angles to the longitudinal axis of the first body, the end 24 at which the second outlet is arranged being in contact with an end wall of the receptacle that is perpendicular to the longitudinal axis. Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to modify Knupp's right end of 14 and connecting tube H with an end wall 24, as taught by Thompson, for the purpose of providing a stopping point for the inner first body 12. The modified Knupp's outlets at 24 can be hooked up to the same ventilation equipment or left as ambient air inlets to meet the needs of the patient.

Regarding claim 4, the modified Knupp of the rejected claim 3 discloses that the second body (Knupp 14) is provided with a through channel (Thompson channel

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between 24 and 32), which has a first outlet (Thompson between 32's bottom and top wall) arranged at the bottom of wall 24 of the receptacle and a second outlet (Thompson top of 24 channel) arranged on the outer surface of the second body, the first outlet of the through channel being arranged in a position in which it faces the second outlet of the inhaling channel at the second position of the first body.

Regarding claim 9, the modified Knupp discloses that the lateral outlet (Knupp 24) and the second outlet (Thompson between 32s top and bottom) of the inhaling channel form a single opening that lie between one end and a portion of the lateral surface of the first body.

Response to Arguments

8. Applicant's arguments with respect to claims 1, 3-9 have been considered but are moot in view of the new grounds of rejection.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gallem et al. (6,481,438) to a metering device, Olsson (6,382,461) to an apparatus and method for metering substance, and Braithwaite (7,207,330) to a delivery system. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL T. YOUNG whose telephone number is (571)270-1481. The examiner can normally be reached on mon-thurs 7 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RACHEL T YOUNG/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771